NTP Historical Controls Report

All Routes And Vehicles

Sprague-Dawley Rats

November 2008

REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

The report combines all the data from all of the historical control studies into one section. To see this data broken up by route and vehicle you must run the "By Route And Vehicle" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male	
	M1
	M2
	М3
	M4
	M5
Fema	ale
	F1
	F2
	F3
	F4
	F5

the data would be shown as:

	Male		Female					
M1	M2	М3	F1	F2	F3			
M4	M5		F4	F5				

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 3

Report Date:11/13/2008

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Species: Sprague-Dawley Rats **Strain:** SD

Version: Nov2008

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Study Summary

				Study	Summary		
Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Columbus Laboratory	059602001	N/A	N/A	0 (0)	0(0)	N/A	TEF evaluation (Binary mixture; PCB 126/PCB 153)
Battelle Columbus Laboratory	059600704	N/A	N/A	0 (0)	0(0)	N/A	TEF evaluation (Dioxin mixture)
Battelle Columbus Laboratory	052030401	N/A	N/A	0 (0)	0(0)	N/A	TEF evaluation (PCB 118)
Battelle Columbus Laboratory	059602202	N/A	N/A	0 (0)	0(0)	N/A	Tef Evaluation (Pcb Mixture; Pcb 126/Pcb 118)
Battelle Columbus Laboratory	059600705	N/A	N/A	0 (0)	0(0)	N/A	TEF evaluation (PECDF (Pentachlorodibenzofuran))
Battelle Columbus Laboratory	059600703	N/A	N/A	0 (0)	0(0)	N/A	TEF evaluation (TCDD)
Battelle Columbus Laboratory	058814806	01/29/03	727	50 (3)	28(665)	606.4	3,3',4,4'-Tetrachloroazobenzene
Battelle Columbus Laboratory	059600701	N/A	N/A	0 (0)	0(0)	N/A	Toxic equivalency factor evaluation ((PCB 126)
Battelle Columbus Laboratory	059602101	N/A	N/A	0 (0)	0(0)	N/A	3,3',4,4',5-pentachlorobiphenyl) Toxic equivalency factor evaluation (PCB 153-2,2'-4,4',5,5'-hexachlorobiphenyl)
				Fen	nale		
Battelle Columbus Laboratory	059602001	09/16/98	729	53 (5)	22(629)	403.6	TEF evaluation (Binary mixture; PCB 126/PCB 153)
Battelle Columbus Laboratory	059600704	06/16/98	729	53 (5)	16(616)	381.2	TEF evaluation (Dioxin mixture)
Battelle Columbus Laboratory	052030401	03/26/04	733	52 (5)	21(616)	383.5	TEF evaluation (PCB 118)
Battelle Columbus Laboratory	059602202	10/14/99	726	53 (5)	27(656)	386.5	Tef Evaluation (Pcb Mixture; Pcb 126/Pcb 118)
Battelle Columbus Laboratory	059600705	04/07/99	728	53 (5)	25(655)	365.7	TEF evaluation (PECDF (Pentachlorodibenzofuran))
Battelle Columbus Laboratory	059600703	06/01/98	731	53 (5)	25(637)	382.6	TEF evaluation (TCDD)
Battelle Columbus Laboratory	058814806	01/30/03	727	50 (5)	25(652)	385.7	3,3',4,4'-Tetrachloroazobenzene
Battelle Columbus Laboratory	059600701	02/26/98	727	53 (5)	15(567)	397.1	Toxic equivalency factor evaluation ((PCB 126)
Battelle Columbus Laboratory	059602101	08/24/98	731	53 (5)	24(641)	394.5	3,3',4,4',5-pentachlorobiphenyl) Toxic equivalency factor evaluation (PCB 153-2,2'-4,4',5,5'-hexachlorobiphenyl)

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Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female	
#All Organs: Benign Tumors								
						49/53 (92%)	45/53 (85%)	43/52 (83%)
		40/50 (000/)				53/53 (100%)	45/53 (85%)	45/53 (85%)
		40/50 (80%)				40/50 (80%)	45/53 (85%)	50/53 (94%)
Overall Incidence	Total	40/50 (80%)	Mean 80%	SD 0%	Total	415/473 (87.74%)	Mean 87.68%	SD 6.46%
All Organs: Malignant Tumors								
						14/53 (26%)	18/53 (34%)	15/52 (29%)
		0.50				16/53 (30%)	12/53 (23%)	13/53 (25%)
		9/50 (18%)				13/50 (26%)	13/53 (25%)	12/53 (23%)
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	126/473 (26.64%)	Mean 26.64%	SD 3.75%
#All Organs:								
Malignant and Benign 1	umors					51/53 (96%)	51/53 (96%)	48/52 (92%)
						53/53 (100%)	48/53 (91%)	47/53 (89%)
		44/50 (88%)				44/50 (88%)	49/53 (92%)	52/53 (98%)
Overall Incidence	Total	44/50 (88%)	Mean 88%	SD 0%	Total	443/473 (93.66%)	Mean 93.62%	SD 4.23%
#All Organs:	•••••			•••••				
Hemangioma						4/50 (00/)	0/50 (00/)	0/50 (00/)
						1/53 (2%) 0/53 (0%)	0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%)
		0/50 (0%)				0/53 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	` '	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
overall incluence	Total	0/50 (0%)	IVICALI U%	3D 0%	Total	1/4/3 (0.21%)	IVIEATI U.21%	3D 0.03%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

11: NOVZUU6

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 5

			Male				Female	
#All Organs: Hemangiosarcoma								
						0/53 (0%) 0/53 (0%)	0/53 (0%) 0/53 (0%)	1/52 (2%) 0/53 (0%)
		1/50 (2%)				0/50 (0%)	2/53 (4%)	1/53 (2%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	4/473 (0.85%)	Mean 0.84%	SD 1.37%
#All O		•••••					• • • • • • • • • • • • • • • • • • • •	
#All Organs: Hemangiosarcoma or He	emangioma							
3.2.2 2	g					1/53 (2%)	0/53 (0%)	1/52 (2%)
		1/50 (2%)				0/53 (0%) 0/50 (0%)	0/53 (0%) 2/53 (4%)	0/53 (0%) 1/53 (2%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	5/473 (1.06%)	2/55 (4%) Mean 1.05%	SD 1.37%
	. 0	.,00 (=,0)				0, 0 (00,0)		
#All Organs: Histiocytic Sarcoma								
						0/53 (0%)	0/53 (0%)	1/52 (2%)
		0/50 (0%)				0/53 (0%) 1/50 (2%)	0/53 (0%) 0/53 (0%)	0/53 (0%) 0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/473 (0.42%)	Mean 0.44%	SD 0.87%
	. 010.	0,00 (0,0)				_, 0 (0,0)		
#All Organs: Leukemia: Lymphocytic	, Monocytic, N	lononuclear, or						
Undifferentiated						0/53 (0%)	0/53 (0%)	0/52 (0%)
						1/53 (2%)	1/53 (2%)	0/53 (0%)
		1/50 (2%)				1/50 (2%)	0/53 (0%)	1/53 (2%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	4/473 (0.85%)	Mean 0.85%	SD 1.01%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 6

			Male				Female					
All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type												
		1/50 (2%)		00.004	-	0/53 (0%) 0/53 (0%) 0/50 (0%)	2/53 (4%) 0/53 (0%) 0/53 (0%)	2/52 (4%) 0/53 (0%) 2/53 (4%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	6/473 (1.27%)	Mean 1.27%	SD 1.9%				
#All Organs: Osteosarcoma												
		0/50 (0%)				0/53 (0%) 0/53 (0%) 0/50 (0%)	0/53 (0%) 0/53 (0%) 1/53 (2%)	0/52 (0%) 0/53 (0%) 0/53 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%				
#All Organs: Osteosarcoma or Oste	eoma					0/53 (0%) 0/53 (0%)	0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 1/473 (0.21%)	1/53 (2%) Mean 0.21%	0/53 (0%) SD 0.63%				
*Adrenal Cortex: Adenoma												
		1/50 (2%)				0/53 (0%) 0/53 (0%) 1/50 (2%)	0/52 (0%) 1/53 (2%) 0/52 (0%)	2/52 (4%) 1/53 (2%) 0/53 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	5/471 (1.06%)	Mean 1.07%	SD 1.4%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 7

			Male				Female	
Adrenal Cortex: Carcinoma								
						0/53 (0%)	0/52 (0%)	1/52 (2%)
		0/50 (00/)				1/53 (2%)	1/53 (2%)	0/53 (0%)
No. 2 and 11 days 2 days 2 a	T-1-1	0/50 (0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	0/52 (0%)	0/53 (0%)
verall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/471 (0.64%)	Mean 0.63%	SD 0.95%
Adrenal Medulla:								
Pheochromocytoma Be	nian							
	9					3/52 (6%)	5/52 (10%)	3/52 (6%)
						3/53 (6%)	4/53 (8%) [′]	3/53 (6%)
		5/50 (10%)				3/50 (6%)	8/52 (15%)	2/53 (4%)
verall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	34/470 (7.23%)	Mean 7.24%	SD 3.44%
Adrenal Medulla:			•••••					
Pheochromocytoma Co	mplex							
·	•					0/52 (0%)	0/52 (0%)	0/52 (0%)
						0/53 (0%)	1/53 (2%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/52 (0%)	0/53 (0%)
verall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/470 (0.21%)	Mean 0.21%	SD 0.63%
Adrenal Medulla:								•••••
Pheochromocytoma Ma	lignant							
	. J					0/52 (0%)	0/52 (0%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/52 (0%)	1/53 (2%)

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 8

			Male				Female					
Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS												
	J , -	, a 3 a , a -				3/52 (6%)	5/52 (10%)	3/52 (6%)				
						3/53 (6%)	5/53 (9%)	3/53 (6%)				
		5/50 (10%)				3/50 (6%)	8/52 (15%)	3/53 (6%)				
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	36/470 (7.66%)	Mean 7.66%	SD 3.33%				
	• • • • • • • • • • • • • • • • • • • •											
Bone Marrow: Lipoma												
Lipoilia .						0/53 (0%)	0/53 (0%)	0/52 (0%)				
						0/53 (0%)	0/53 (0%)	0/53 (0%)				
		0/50 (0%)				0/50 (0%)	0/53 (0%)	1/53 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%				
#Bone: Osteosarcoma												
Osteosarconia						0/53 (0%)	0/53 (0%)	0/52 (0%)				
						0/53 (0%)	0/53 (0%)	0/53 (0%)				
		0/50 (0%)				0/50 (0%)	1/53 (2%)	0/53 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%				
Bone: Osteosarcoma or Osteoma	a											
						0/53 (0%)	0/53 (0%)	0/52 (0%)				
						0/53 (0%)	0/53 (0%)	0/53 (0%)				
		0/50 (0%)				0/50 (0%)	1/53 (2%)	0/53 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%				

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 9

			Male				Female	
*Brain: Astrocytoma Benign								
						0/53 (0%)	0/53 (0%)	0/52 (0%)
		4/50 (20/)				0/53 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Maan 20/	CD 00/	Total	0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/473 (0%)	Mean 0%	SD 0%
Brain: Astrocytoma Malignant								
, ,						0/53 (0%)	0/53 (0%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	2/53 (4%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 1.26%
Brain:								
Medulloblastoma Mal						0/53 (0%)	0/53 (0%)	0/52 (0%)
						1/53 (2%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
*Brain:								
Oligodendroglioma Malign	ant							
						0/53 (0%)	0/53 (0%)	0/52 (0%)
		0/50 (00/)				0/53 (0%)	0/53 (0%)	0/53 (0%)
	-	0/50 (0%)		05.00/	-	0/50 (0%)	1/53 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories **Species:** Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 10

			Male				Female	
*Brain:								
Oligodendroglioma, Gliom	ia, or Astroc	ytoma				0/52 (00/)	0/52 (00/)	0/50 (00/)
						0/53 (0%) 0/53 (0%)	0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%)
		1/50 (2%)				0/50 (0%)	3/53 (6%)	0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	3/473 (0.63%)	Mean 0.63%	SD 1.89%
		,				,		
Clitoral/Preputial Gland: Adenoma								
						1/53 (2%)	0/51 (0%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)	0/50 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/465 (0.22%)	Mean 0.21%	SD 0.63%
Clitoral/Preputial Gland:			•••••		•••••			
Carcinoma or Adenoma						1/52 (20/)	0/51 (00/)	0/52 (09/)
						1/53 (2%) 0/53 (0%)	0/51 (0%) 0/53 (0%)	0/52 (0%) 0/50 (0%)
		0/50 (0%)				0/50 (0%)	0/50 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/465 (0.22%)	Mean 0.21%	SD 0.63%
#Ear: Neural Crest Tumor								
						0/53 (0%)	0/53 (0%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	1/53 (2%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 11

			Male				Female	
#Eye: Schwannoma Malignant								
		1/50 (2%)				0/53 (0%) 0/53 (0%) 0/50 (0%)	0/53 (0%) 0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%) 0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/473 (0%)	Mean 0%	SD 0%
*Heart:	• • • • • • • • • • • • • • • • • • • •							
Hemangiosarcoma		0/50 (00/)				0/53 (0%) 0/53 (0%)	0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%)
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 1/471 (0.21%)	0/52 (0%) Mean 0.21%	1/52 (2%) SD 0.64%
*Heart:			•••••			•••••	•••••	
Schwannoma Malignant		0/50 (0%)				0/53 (0%) 0/53 (0%) 0/50 (0%)	2/53 (4%) 1/53 (2%) 0/52 (0%)	0/52 (0%) 0/53 (0%) 0/52 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/471 (0.64%)	Mean 0.63%	SD 1.33%
#Intestine Large: Cecum: Leiomyoma								
20.01117011114		0/50 /00/				0/53 (0%) 0/53 (0%)	0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%)
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 1/473 (0.21%)	0/53 (0%) Mean 0.21%	1/53 (2%) SD 0.63%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 12

			Male				Female	
#Intestine Large: Colon/Rectum Carcinoma	1:							
						0/53 (0%)	1/53 (2%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
#Intestine Large: Colon/Rectum Carcinoma or Adenoma	1:		•••••				•••••	
Carcinoma or Adenoma						0/53 (0%)	1/53 (2%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
#Intestine Small: Duodenum:			•••••				•••••	
Carcinoma						0/50 (00/)	0/50 (00/)	0/50 (00/)
						0/53 (0%) 0/53 (0%)	0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%)
		0/50 (0%)				1/50 (2%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%
#Intestine Small: Jejunum:								
Leiomyosarcoma								
-						1/53 (2%)	1/53 (2%)	0/52 (0%)
		0.450 (004)				0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.83%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 13

			Male				Female	
Intestine Small: Site Unspe Carcinoma	ecified:							
						0/53 (0%)	0/53 (0%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				1/50 (2%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%
Intestine Small: Site Unspe	ecified:	•••••	••••••		•••••	•••••		•••••
Carcinoma or Adenoma								
						0/53 (0%)	0/53 (0%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				1/50 (2%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%
Intestine Small: Site Unspe			•••••		•••••	•••••		•••••
Leiomyosarcoma								
						1/53 (2%)	1/53 (2%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.83%
Islets, Pancreatic: Adenoma						•••••		
Adenoma						1/53 (2%)	1/52 (2%)	0/52 (0%)
						1/53 (2%)	0/53 (0%)	1/51 (2%)
		2/50 (4%)				0/50 (0%)	0/52 (0%)	1/53 (2%)
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	5/469 (1.07%)	Mean 1.06%	SD 1.01%
Total Illolacilos	TOTAL	2/00 (4/0)	Wican 7/0	00 070	iotal	0/400 (1.07/0)	WCarr 1.0070	3D 1.0170

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 14

			Male				Female	
Islets, Pancreatic: Carcinoma								
						0/53 (0%)	1/52 (2%)	0/52 (0%)
						1/53 (2%)	0/53 (0%)	1/51 (2%)
		0/50 (0%)				0/50 (0%)	0/52 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/469 (0.64%)	Mean 0.64%	SD 0.96%
Islets, Pancreatic: Carcinoma or Adenoma								
						1/53 (2%)	2/52 (4%)	0/52 (0%)
						2/53 (4%)	0/53 (0%)	2/51 (4%)
		2/50 (4%)				0/50 (0%)	0/52 (0%)	1/53 (2%)
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	8/469 (1.71%)	Mean 1.7%	SD 1.78%
Kidney: Renal Tubule: Adenoma								
Adenoma						1/53 (2%)	0/52 (0%)	0/52 (0%)
						1/53 (2%)	0/52 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/472 (0.42%)	Mean 0.42%	SD 0.83%
Kidney: Renal Tubule: Carcinoma		•••••			•••••			
ou. oou						0/53 (0%)	1/52 (2%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/472 (0.21%)	Mean 0.21%	SD 0.64%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 15

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma								
						1/53 (2%)	1/52 (2%)	0/52 (0%)
		0/50 (00/)				1/53 (2%)	0/53 (0%)	0/53 (0%)
Overall Insidence	Tatal	0/50 (0%)	Maaa 00/	CD 00/	Tatal	0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/472 (0.64%)	Mean 0.63%	SD 0.95%
*Kidney: Renal Tubule: Hemangiosarcoma								
5						0/53 (0%)	0/52 (0%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	1/53 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/472 (0.21%)	Mean 0.21%	SD 0.63%
*Kidney: Renal Tubule:			•••••				•••••	
Lipoma						0/53 (0%)	0/52 (0%)	0/52 (0%)
						0/53 (0%)	1/53 (2%)	0/53 (0%)
		0/50 (0%)				1/50 (2%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/472 (0.42%)	Mean 0.43%	SD 0.86%
*Kidney: Renal Tubule: Nephroblastoma								
i te pili obiastollia						0/53 (0%)	1/52 (2%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	1/53 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/472 (0.42%)	Mean 0.42%	SD 0.84%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 16

			Male				Female	
Liver: Cholangiocarcinoma								
•						0/53 (0%)	0/53 (0%)	0/52 (0%)
		0/50 (00/)				0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)	• • • • • • • • • • • • • • • • • • • •	05.00/		1/50 (2%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%
Liver: Cholangioma							•••••	•••••
3						0/53 (0%)	0/53 (0%)	1/52 (2%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.64%
Liver:								
Hemangioma						1/53 (2%)	0/52 (00/)	0/50 (00/)
						1/53 (2%) 0/53 (0%)	0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
Liver: Hepatocellular Adenoma								•••••
ricpatocellulai Auelloilla						0/53 (0%)	0/53 (0%)	0/52 (0%)
						2/53 (4%)	1/53 (2%)	0/53 (0%)
		0/50 (0%)				2/50 (4%)	1/53 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	6/473 (1.27%)	Mean 1.28%	SD 1.68%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 17

			Male				Female	
*Liver: Hepatocellular Carcin	oma or Henstocc	allular Adenoma						
nepatocendiai Carcini	oma or nepatoce	eliulai Auelioilia				0/53 (0%)	0/53 (0%)	0/52 (0%)
						2/53 (4%)	1/53 (2%)	0/53 (0%)
		0/50 (0%)				2/50 (4%)	1/53 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	6/473 (1.27%)	Mean 1.28%	SD 1.68%
		•••••		•••••				•••••
Liver: Hepatocellular Carcine	oma Henatocelli	ular Adenoma or						
Hepatoblastoma	oma, nepatocem	ulai Adelioilla, oi						
						0/53 (0%)	0/53 (0%)	0/52 (0%)
						2/53 (4%)	1/53 (2%)	0/53 (0%)
		0/50 (0%)				2/50 (4%)	1/53 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	6/473 (1.27%)	Mean 1.28%	SD 1.68%
*Lung:						• • • • • • • • • • • • • • • • • • • •		
Alveolar/Bronchiolar	Adenoma							
Aiveolai/Biolicillolai /	Adenoma					0/53 (0%)	0/53 (0%)	0/51 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		1/50 (2%)				0/50 (0%)	1/53 (2%)	1/52 (2%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/471 (0.42%)	Mean 0.42%	SD 0.84%
		•••••		•••••	• • • • • • • • • • • • • • • • • • • •		•••••	•••••
Lung: Alveolar/Bronchiolar (Carcinoma							
,	Ja. J					0/53 (0%)	0/53 (0%)	0/51 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		1/50 (2%)				0/50 (0%)	0/53 (0%)	0/52 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/471 (0%)	Mean 0%	SD 0%
		(= /0)		02 070		2 (3.3)		32 373

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

131011: 11012000

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats **Strain:** SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 18

			Male				Female	
*Lung: Alveolar/Bronchiolar Carci Adenoma	inoma or Alv	/eolar/Bronchiolar						
						0/53 (0%) 0/53 (0%)	0/53 (0%) 0/53 (0%)	0/51 (0%) 0/53 (0%)
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 2/471 (0.42%)	1/53 (2%) Mean 0.42%	1/52 (2%) SD 0.84%
#Lymph Node, Mesenteric:			•••••			•••••	•••••	
Hemangiosarcoma		0/50 (00/)				0/53 (0%) 0/53 (0%)	0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%)
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 1/473 (0.21%)	1/53 (2%) Mean 0.21%	0/53 (0%) SD 0.63%
#Mammary Gland: Adenoma								
Adenoma		0/50 (0%)				2/53 (4%) 2/53 (4%) 1/50 (2%)	0/53 (0%) 1/53 (2%) 2/53 (4%)	0/52 (0%) 2/53 (4%) 2/53 (4%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	12/473 (2.54%)	Mean 2.53%	SD 1.63%
// Oleve d								
#Mammary Gland: Carcinoma								
		0/50 (0%)				8/53 (15%) 5/53 (9%) 4/50 (8%)	6/53 (11%) 5/53 (9%) 6/53 (11%)	2/52 (4%) 4/53 (8%) 8/53 (15%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	48/473 (10.15%)	Mean 10.12%	SD 3.6%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 19

			Male				Female	
#Mammary Gland: Carcinoma or Adenoma								
						10/53 (19%)	6/53 (11%)	2/52 (4%)
						6/53 (11%)	6/53 (11%)	6/53 (11%)
		0/50 (0%)				5/50 (10%)	7/53 (13%)	9/53 (17%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	57/473 (12.05%)	Mean 12.02%	SD 4.27%
#Mammary Gland: Fibroadenoma				•••••				
						40/53 (75%)	34/53 (64%)	25/52 (48%)
						42/53 (79%)	34/53 (64%)	33/53 (62%)
		0/50 (0%)				31/50 (62%)	39/53 (74%)	41/53 (77%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	319/473 (67.44%)	Mean 67.37%	SD 9.96%
#Mammary Gland:			•••••					
Fibroma, Fibroadenoma or	r Adenoma					40/50 (750/)	24/52 (640/)	OF/FO (400/)
						40/53 (75%) 42/53 (79%)	34/53 (64%) 35/53 (66%)	25/52 (48%) 35/53 (66%)
		0/50 (0%)				31/50 (62%)	40/53 (75%)	41/53 (77%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	323/473 (68.29%)	Mean 68.21%	SD 9.88%
		0/30 (0/8)				323/473 (00.2970)	Weatt 00.2176	9.00%
#Mammary Gland:	`oroinomo o	or Adonomo						
Fibroma, Fibroadenoma, C	arcinoma, c	n Aucitotta				42/53 (79%)	37/53 (70%)	27/52 (52%)
						42/53 (79%)	38/53 (72%)	35/53 (66%)
		0/50 (0%)				32/50 (64%)	42/53 (79%)	43/53 (81%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	338/473 (71.46%)	Mean 71.37%	SD 9.65%
	10101	3,30 (0,70)	Modil 070	32 0,0	10141	(11.1070)	1110411 1110170	35 0.0070

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 20

			Male				Female	
#Mesentery: Schwannoma Malignant								
						0/53 (0%) 0/53 (0%)	0/53 (0%) 0/53 (0%)	0/52 (0%) 1/53 (2%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
Oral Cavity (Oral Mucosa, Tor Squamous Cell Carcinoma	ngue, Phary							
						0/53 (0%)	1/53 (2%)	0/52 (0%)
		1/50 (2%)				1/53 (2%) 0/50 (0%)	1/53 (2%) 0/53 (0%)	1/53 (2%) 0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	4/473 (0.85%)	Mean 0.84%	SD 0.99%
Oral Cavity (Oral Mucosa, Tor Squamous Cell Carcinoma Papilloma						0/53 (0%)	1/53 (2%)	0/52 (0%)
						1/53 (2%)	1/53 (2%)	1/53 (2%)
		1/50 (2%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	4/473 (0.85%)	Mean 0.84%	SD 0.99%
#Oral Mucosa: Squamous Cell Carcinoma				•••••		•••••		
Squamous Cen Carcinoma						0/53 (0%)	1/53 (2%)	0/52 (0%)
						1/53 (2%)	1/53 (2%)	1/53 (2%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	0/53 (0%) Mean 0.84%	0/53 (0%) SD 0.99%
overali incidence	Total	1/50 (2%)	IVIEATI 2%	SD 0%	Total	4/473 (0.85%)	iviean 0.04%	3D 0.99%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 21

Male			Female	
Ovary:				
Cystadenoma			- ()	
		0/53 (0%)	0/52 (0%)	0/52 (0%)
		0/53 (0%)	0/53 (0%)	0/51 (0%)
		0/50 (0%)	0/52 (0%)	1/53 (2%)
verall Incidence	Total	1/469 (0.21%)	Mean 0.21%	SD 0.63%
^				
Ovary: Granulosa Cell Tumor Malignant				
Grandiosa Gen Turnor Mangriant		1/53 (2%)	0/52 (0%)	0/52 (0%)
		1/53 (2%)	0/53 (0%)	0/51 (0%)
		1/50 (2%)	0/52 (0%)	0/53 (0%)
Overall Incidence	Total	3/469 (0.64%)	Mean 0.64%	SD 0.96%
		,		
Ovary:				
Granulosa Cell Tumor: Benign, Malignant, NOS				
		1/53 (2%)	0/52 (0%)	0/52 (0%)
		1/53 (2%)	0/53 (0%)	0/51 (0%)
		1/50 (2%)	0/52 (0%)	0/53 (0%)
Overall Incidence	Total	3/469 (0.64%)	Mean 0.64%	SD 0.96%
O				
Ovary: Luteoma				
Euroonia		0/53 (0%)	0/52 (0%)	1/52 (2%)
		1/53 (2%)	1/53 (2%)	0/51 (0%)
		0/50 (0%)	0/52 (0%)	0/53 (0%)
Overall Incidence	Total	3/469 (0.64%)	Mean 0.63%	SD 0.95%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 22

			Male				Female	
Pancreas: Adenoma								
						0/53 (0%)	0/52 (0%)	0/52 (0%)
		0/50 (400/)				0/53 (0%)	0/53 (0%)	0/51 (0%)
S	T-1-1	9/50 (18%)	Maria 400/	00.00/	T-1-1	0/50 (0%)	1/51 (2%)	0/53 (0%)
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	1/468 (0.21%)	Mean 0.22%	SD 0.65%
Pancreas: Carcinoma								
						0/53 (0%)	0/52 (0%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/51 (0%)
		0/50 (0%)				1/50 (2%)	0/51 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/468 (0.21%)	Mean 0.22%	SD 0.67%
Pancreas:				•••••	••••••			
Carcinoma or Adenoma						0/52 (00/)	0/50 (00/)	0/50 (00/)
						0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%)	0/52 (0%) 0/51 (0%)
		9/50 (18%)				1/50 (2%)	1/51 (2%)	0/53 (0%)
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	2/468 (0.43%)	Mean 0.44%	SD 0.87%
Parathyroid Gland:								
Adenoma								
						0/45 (0%)	1/50 (2%)	0/47 (0%)
		(221)				0/50 (0%)	0/49 (0%)	0/46 (0%)
		1/43 (2%)				0/46 (0%)	0/47 (0%)	0/49 (0%)
Overall Incidence	Total	1/43 (2.33%)	Mean 2.33%	SD 0%	Total	1/429 (0.23%)	Mean 0.22%	SD 0.67%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 23

			Male				Female	
Peripheral Nerve: Schwannoma Malignant								
						0/53 (0%)	0/53 (0%)	0/52 (0%)
		0.50 (00.1)				0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				1/50 (2%)	0/53 (0%)	0/53 (0%)
verall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%
Peripheral Nerve:		•••••		• • • • • • • • • • • • • • • • • • • •				
Schwannoma: Benign, N	/alignant_NOS	;						
Commanifornia. Domgii, ii	nangnam, moc					0/53 (0%)	0/53 (0%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				1/50 (2%)	0/53 (0%)	0/53 (0%)
verall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%
Pituitary Gland: Pars Distal	is or Unspecif	ied Site:						
Adenoma								
						22/53 (42%)	28/53 (53%)	17/52 (33%)
		40/50 (000/)				30/53 (57%)	15/53 (28%)	25/53 (47%)
		13/50 (26%)	•• •••	00.007		13/50 (26%)	15/51 (29%)	18/53 (34%)
verall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	183/471 (38.85%)	Mean 38.72%	SD 11.26%
Pituitary Gland: Pars Distal	is or Unspecif	ied Site:			•••••			
Carcinoma								
						1/53 (2%)	0/53 (0%)	2/52 (4%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/51 (0%)	0/53 (0%)
				SD 0%		3/471 (0.64%)	Mean 0.64%	SD 1.36%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 24

			Male				Female	
Pituitary Gland: Pars Dista Carcinoma or Adenoma		ied Site:						
caromonia or Austronia	•					23/53 (43%)	28/53 (53%)	19/52 (37%)
						30/53 (57%)	15/53 (28%)	25/53 (47%)
		13/50 (26%)				13/50 (26%)	15/51 (29%)	18/53 (34%)
verall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	186/471 (39.49%)	Mean 39.36%	SD 11.14%
Pituitary Gland: Pars Inter Adenoma	media:							
						0/53 (0%)	0/53 (0%)	0/52 (0%)
						1/53 (2%)	0/53 (0%)	2/53 (4%)
		0/50 (0%)				1/50 (2%)	1/51 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	5/471 (1.06%)	Mean 1.07%	SD 1.39%
Pituitary Gland: Pars Inter				•••••			•••••	
Carcinoma or Adenoma	3							
						0/53 (0%)	0/53 (0%)	0/52 (0%)
		0/50 (00/)				1/53 (2%)	0/53 (0%)	2/53 (4%)
	-	0/50 (0%)		OD 00/	-	1/50 (2%)	1/51 (2%)	0/53 (0%)
verall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	5/471 (1.06%)	Mean 1.07%	SD 1.39%
Prostate:	•••••				•••••			
Adenoma								
		5/50 (10%)						
verall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 25

			Male				Female	
*Prostate: Carcinoma or Adenoma		5/50 (10%)						
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%				
*Salivary Glands: Schwannoma Malignant						0/53 (0%) 0/53 (0%)	0/53 (0%) 0/53 (0%)	0/51 (0%) 0/51 (0%)
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/466 (0%)	0/51 (0%) Mean 0%	0/51 (0%) SD 0%
#Skeletal Muscle: Fibrous Histiocytoma		0/50 (0%)				1/53 (2%) 0/53 (0%) 0/50 (0%)	0/53 (0%) 0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%) 0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)				0/53 (0%) 0/53 (0%) 1/50 (2%)	0/53 (0%) 0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%) 0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 26

			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma oi	r Rhabdomyom	a						
						0/53 (0%) 0/53 (0%)	0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%)
		0/50 (0%)				1/50 (2%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%
 Skin:								
Basal Cell Adenoma								
						0/53 (0%) 1/53 (2%)	0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%)
		1/50 (2%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
#Skin:								
Basal Cell Adenoma or	Basosquamous	s Tumor Benign						
						0/53 (0%) 1/53 (2%)	0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%)
		1/50 (2%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
 #Skin:						•••••		
Basal Cell Adenoma, Ba	asosquamous 1	Tumor Benign, or						
Trichoepithelioma						0/52 (00/)	0/52 (00/)	0/50 (00/)
						0/53 (0%) 1/53 (2%)	0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%)
		1/50 (2%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female	
#Skin:								
Basal Cell Carcinoma						0/53 (0%)	0/53 (0%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	1/53 (2%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
#Skin: Basal Cell Carcinoma NOS)	or Basosquamo	us Tumor (malignant or						
						0/53 (0%)	0/53 (0%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	1/53 (2%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
#Skin: Basal Cell Carcinoma, Tumor (benign, maligi		noma, Basosquamous				0/53 (0%)	0/53 (0%)	0/52 (0%)
Basal Cell Carcinoma,		noma, Basosquamous Trichoepithelioma				1/53 (2%)	0/53 (0%)	1/53 (2%)
Basal Cell Carcinoma,		noma, Basosquamous	Mean 2%	SD 0%	Total			
Basal Cell Carcinoma, Tumor (benign, malign Overall Incidence #Skin: Basal or Sq. Cell Carc or B), Basal Cell Aden	Total cinoma, Carcinona, Adenoma,	noma, Basosquamous Trichoepithelioma 1/50 (2%) 1/50 (2%)		SD 0%	Total	1/53 (2%) 0/50 (0%)	0/53 (0%) 0/53 (0%)	1/53 (2%) 0/53 (0%)
Basal Cell Carcinoma, Tumor (benign, malign Overall Incidence #Skin: Basal or Sq. Cell Carc	Total cinoma, Carcinona, Adenoma,	noma, Basosquamous Trichoepithelioma 1/50 (2%) 1/50 (2%)		SD 0%	Total	1/53 (2%) 0/50 (0%)	0/53 (0%) 0/53 (0%)	1/53 (2%) 0/53 (0%) SD 0.83%
Basal Cell Carcinoma, Tumor (benign, malign Overall Incidence #Skin: Basal or Sq. Cell Carc or B), Basal Cell Aden	Total cinoma, Carcinona, Adenoma,	noma, Basosquamous Trichoepithelioma 1/50 (2%) 1/50 (2%)		SD 0%	Total	1/53 (2%) 0/50 (0%) 2/473 (0.42%)	0/53 (0%) 0/53 (0%) Mean 0.42%	1/53 (2%) 0/53 (0%) SD 0.83%
Basal Cell Carcinoma, Tumor (benign, malign Overall Incidence #Skin: Basal or Sq. Cell Carc or B), Basal Cell Aden	Total cinoma, Carcinona, Adenoma,	noma, Basosquamous Trichoepithelioma 1/50 (2%) 1/50 (2%)		SD 0%	Total	1/53 (2%) 0/50 (0%) 2/473 (0.42%) 0/53 (0%)	0/53 (0%) 0/53 (0%) Mean 0.42%	1/53 (2%) 0/53 (0%) SD 0.83%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 28

			Male				Female	
Skin: Fibroma								
						2/53 (4%)	1/53 (2%)	2/52 (4%)
		5/50 (10%)				1/53 (2%) 0/50 (0%)	0/53 (0%) 1/53 (2%)	1/53 (2%) 0/53 (0%)
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	8/473 (1.69%)	Mean 1.69%	SD 1.49%
		, ,				` ,		
Skin:								
Fibroma, Fibrosarcoma, S Fibrous Histiocytoma	arcoma, Myx	coma, Myxosarcoma, or						
Fibrous Histocytoma						2/53 (4%)	2/53 (4%)	2/52 (4%)
						1/53 (2%)	0/53 (0%)	1/53 (2%)
		5/50 (10%)				0/50 (0%)	1/53 (2%)	0/53 (0%)
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	9/473 (1.9%)	Mean 1.89%	SD 1.64%
Skin:		••••••						
Fibrosarcoma								
						0/53 (0%)	1/53 (2%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
verall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
Skin:								
Fibrosarcoma, Sarcoma, I Histiocytoma	Myxosarcom	a, or Fibrous						
Histocytolila						0/53 (0%)	1/53 (2%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 29

			Male				Female	
#Skin: Hemangiosarcoma								
						0/53 (0%)	0/53 (0%)	1/52 (2%)
		4/50 (00/)				0/53 (0%)	0/53 (0%)	0/53 (0%)
		1/50 (2%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.64%
∜Skin: Keratoacanthoma								
						0/53 (0%)	0/53 (0%)	1/52 (2%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		2/50 (4%)				0/50 (0%)	1/53 (2%)	0/53 (0%)
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.84%
#Skin: Neural Crest Tumor								
Neural Crest Tullion						0/53 (0%)	0/53 (0%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/53 (0%)
		1/50 (2%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/473 (0%)	Mean 0%	SD 0%
#Skin:		undiament on NOC)						
Neurofibrosarcoma or Sc	nwannoma (r	nanghant or NOS)				0/53 (0%)	0/53 (0%)	1/52 (2%)
						0/53 (0%)	0/53 (0%)	1/52 (2%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.84%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female	
#Skin: Neurofibrosarcoma, Neumalignant or NOS)	ırofibroma, or	Schwannoma (benign,						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/53 (0%) 0/53 (0%) 0/50 (0%) 2/473 (0.42%)	0/53 (0%) 0/53 (0%) 0/53 (0%) Mean 0.42%	1/52 (2%) 1/53 (2%) 0/53 (0%) SD 0.84%
#Skin: Schwannoma Malignant								
		0/50 (0%)				0/53 (0%) 0/53 (0%) 0/50 (0%)	0/53 (0%) 0/53 (0%) 0/53 (0%)	1/52 (2%) 1/53 (2%) 0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.84%
#Skin: Squamous Cell Carcino Basosquamous Tumor (0/53 (0%)	0/53 (0%)	0/52 (0%)
		0/50 (0%)				0/53 (0%) 0/50 (0%)	0/53 (0%) 0/53 (0%)	1/53 (2%) 0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
#Skin: Squamous Cell Papillon	na							
oquamous cen Fapinon	ια	0/50 (0%)				0/53 (0%) 1/53 (2%) 0/50 (0%)	0/53 (0%) 0/53 (0%) 0/53 (0%)	0/52 (0%) 0/53 (0%) 0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories **Species:** Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 31

			Male				Female	
#Skin: Squamous Cell Papillom	a or Papilloma	a				0/53 (0%)	0/53 (0%)	0/52 (0%)
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/53 (2%) 0/50 (0%) 1/473 (0.21%)	0/53 (0%) 0/53 (0%) Mean 0.21%	0/53 (0%) 0/53 (0%) 0/53 (0%) SD 0.63%
#Skin: Squamous Cell Papillom Carcinoma or Keratoaca		Squamous Cell						•••••
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/53 (0%) 1/53 (2%) 0/50 (0%) 3/473 (0.63%)	0/53 (0%) 0/53 (0%) 1/53 (2%) Mean 0.63%	1/52 (2%) 0/53 (0%) 0/53 (0%) SD 0.95%
#Skin:								
Squamous Cell Papillom Overall Incidence	a, Papilloma , o	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/53 (0%) 1/53 (2%) 0/50 (0%) 3/473 (0.63%)	0/53 (0%) 0/53 (0%) 1/53 (2%) Mean 0.63%	1/52 (2%) 0/53 (0%) 0/53 (0%) SD 0.95%
#Stomach, Forestomach: Squamous Cell Carcinon	 ma							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/53 (0%) 1/53 (2%) 0/50 (0%) 2/473 (0.42%)	0/53 (0%) 0/53 (0%) 0/53 (0%) Mean 0.42%	0/52 (0%) 1/53 (2%) 0/53 (0%) SD 0.83%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 32

			Male				Female				
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 0/53 (0%) 0/53 (0%) 0/52 (0%)											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/53 (0%) 1/53 (2%) 0/50 (0%) 2/473 (0.42%)	0/53 (0%) 0/53 (0%) 0/53 (0%) Mean 0.42%	0/52 (0%) 1/53 (2%) 0/53 (0%) SD 0.83%			
Testes: Adenoma		2/50 (4%)									
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%							
Thymus: Thymoma Benign		0/48 (0%)				0/53 (0%) 1/53 (2%) 0/50 (0%)	0/52 (0%) 0/53 (0%) 0/50 (0%)	0/51 (0%) 0/51 (0%) 0/48 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	1/461 (0.22%)	Mean 0.21%	SD 0.63%			
Thymus: Thymoma: Benign, Ma	lignant, NOS						- 1				
		0/48 (0%)				0/53 (0%) 1/53 (2%) 0/50 (0%)	0/52 (0%) 0/53 (0%) 0/50 (0%)	0/51 (0%) 0/51 (0%) 0/48 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	1/461 (0.22%)	Mean 0.21%	SD 0.63%			

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 33

			Male				Female	
Thyroid Gland: C-Cell: Adenoma								
						10/53 (19%)	17/53 (32%)	9/51 (18%)
						9/53 (17%)	13/53 (25%)	20/52 (38%)
		13/50 (26%)				10/50 (20%)	15/52 (29%)	16/51 (31%)
verall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	119/468 (25.43%)	Mean 25.42%	SD 7.63%
Fhymaid Cland, C Call.			•••••					• • • • • • • • • • • • • • • • • • • •
Thyroid Gland: C-Cell: Carcinoma								
Carcillonia						4/53 (8%)	2/53 (4%)	2/51 (4%)
						4/53 (8%)	2/53 (4%)	1/52 (2%)
		1/50 (2%)				1/50 (2%)	0/52 (0%)	2/51 (4%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	18/468 (3.85%)	Mean 3.82%	SD 2.48%
Thursday Claude C. Calle			•••••					
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
Carcillonia of Adenonia						13/53 (25%)	18/53 (34%)	11/51 (22%)
						13/53 (25%)	15/53 (28%)	21/52 (40%)
		13/50 (26%)				11/50 (22%)	15/52 (29%)	18/51 (35%)
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	135/468 (28.85%)	Mean 28.82%	SD 6.5%
Thyroid Gland: Follicular Cell: Adenoma								
						0/53 (0%)	0/53 (0%)	1/51 (2%)
						0/53 (0%)	0/53 (0%)	1/52 (2%)
		0/50 (0%)				0/50 (0%)	0/52 (0%)	0/51 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/468 (0.43%)	Mean 0.43%	SD 0.86%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 34

			Male				Female	
Thyroid Gland: Follicular Cell: Carcinoma								
						0/53 (0%)	0/53 (0%)	0/51 (0%)
						1/53 (2%)	0/53 (0%)	0/52 (0%)
		0/50 (0%)				0/50 (0%)	0/52 (0%)	0/51 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/468 (0.21%)	Mean 0.21%	SD 0.63%
Thyroid Gland: Follicular Cell:			•••••			•••••		•••••
Carcinoma or Adenoma								
						0/53 (0%)	0/53 (0%)	1/51 (2%)
						1/53 (2%)	0/53 (0%)	1/52 (2%)
		0/50 (0%)				0/50 (0%)	0/52 (0%)	0/51 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/468 (0.64%)	Mean 0.64%	SD 0.96%
≠Tooth:						•••••		•••••
Fibrosarcoma								
						0/53 (0%)	1/53 (2%)	0/52 (0%)
		0/50 (00/)				0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
#Tooth:								
Neurofibrosarcoma						0/50 (00/)	0/50 (00/)	0/50 (00/)
						0/53 (0%)	0/53 (0%)	0/52 (0%)
		0/50 (0%)				0/53 (0%) 0/50 (0%)	0/53 (0%) 0/53 (0%)	0/53 (0%) 1/53 (2%)
Overell Incidence	Total	` '	Maan 00/	CD 00/	Total	` '	` '	` ,
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 35

			Male				Female	
#Tooth: Odontoma								
						0/53 (0%)	0/53 (0%)	1/52 (2%)
		0/50 (00/)				0/53 (0%)	0/53 (0%)	0/53 (0%)
O	T-1-1	0/50 (0%)	M 00/	00.00/	T-1-1	0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.64%
*Urinary Bladder: Carcinoma or Papilloma								
•						1/53 (2%)	0/52 (0%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/52 (0%)
		0/50 (0%)				0/50 (0%)	0/51 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/469 (0.21%)	Mean 0.21%	SD 0.63%
Urinary Bladder:								
Papilloma						1/53 (2%)	0/52 (0%)	0/52 (0%)
						0/53 (0%)	0/53 (0%)	0/52 (0%)
		0/50 (0%)				0/50 (0%)	0/51 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/469 (0.21%)	Mean 0.21%	SD 0.63%
#Uterus:								
Adenoma						0/53 (0%)	0/53 (0%)	0/52 (0%)
						0/53 (0%)	2/53 (4%)	0/53 (0%)
						0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence					Total	2/473 (0.42%)	Mean 0.42%	SD 1.26%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 36

	Male			Female	
Uterus:					
Carcinoma					
			0/53 (0%)	1/53 (2%)	2/52 (4%)
			1/53 (2%)	1/53 (2%)	0/53 (0%)
		-	1/50 (2%)	0/53 (0%)	0/53 (0%)
overall Incidence		Total	6/473 (1.27%)	Mean 1.28%	SD 1.36%
Uterus:					
Fibroma					
			0/53 (0%)	0/53 (0%)	0/52 (0%)
			0/53 (0%)	1/53 (2%)	0/53 (0%)
			0/50 (0%)	0/53 (0%)	0/53 (0%)
overall Incidence		Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
Uterus: Leiomyoma					
Leioniyoma			0/53 (0%)	0/53 (0%)	0/52 (0%)
			0/53 (0%)	0/53 (0%)	1/53 (2%)
			0/50 (0%)	0/53 (0%)	0/53 (0%)
overall Incidence		Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
			,		
					•••••
Uterus:					
Leiomyosarcoma			0/50 (00/)	4/50 (00/)	0/50 (00/)
			0/53 (0%)	1/53 (2%)	0/52 (0%)
			0/53 (0%)	0/53 (0%)	0/53 (0%)
		-	0/50 (0%)	0/53 (0%)	0/53 (0%)
overall Incidence		Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 37

	Male	Female			
#Uterus: Polyp Stromal					
1 diyp diromai			8/53 (15%)	4/53 (8%)	3/52 (6%)
			11/53 (21%)	9/53 (17%)	11/53 (21%)
			8/50 (16%)	4/53 (8%)	7/53 (13%)
Overall Incidence		Total	65/473 (13.74%)	Mean 13.74%	SD 5.66%
#Uterus:					
Sarcoma Stromal or Polyp Stromal			8/53 (15%)	4/53 (8%)	3/52 (6%)
			11/53 (21%)	9/53 (17%)	11/53 (21%)
			8/50 (16%)	4/53 (8%)	7/53 (13%)
Overall Incidence		Total	65/473 (13.74%)	Mean 13.74%	SD 5.66%
#Uterus:					
Schwannoma Malignant			0/53 (0%)	1/53 (2%)	1/52 (2%)
			1/53 (2%)	0/53 (0%)	1/53 (2%)
			0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence		Total	4/473 (0.85%)	Mean 0.84%	SD 1%
#Uterus: Squamous Cell Carcinoma					
oquamous cen caremonia			1/53 (2%)	0/53 (0%)	0/52 (0%)
			0/53 (0%)	0/53 (0%)	0/53 (0%)
			1/50 (2%)	0/53 (0%)	0/53 (0%)
Overall Incidence		Total	2/473 (0.42%)	Mean 0.43%	SD 0.86%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 38

Male	Male		Female			
Uterus:						
Squamous Cell Papilloma		0/50	(00()	4/50 (00/)	0/50 (00/)	
		0/53	(0%)	1/53 (2%)	0/52 (0%)	
		0/53	(0%)	0/53 (0%)	1/53 (2%)	
		0/50	(0%)	0/53 (0%)	0/53 (0%)	
Overall Incidence	Total	2/473 (0.42%)	Mean 0.42%	SD 0.83%	
∜Vagina: Polyp						
		0/53	(0%)	0/53 (0%)	1/52 (2%)	
		0/53	(0%)	0/53 (0%)	0/53 (0%)	
		0/50	(0%)	0/53 (0%)	0/53 (0%)	
Overall Incidence	Total	1/473 (0.21%)	Mean 0.21%	SD 0.64%	
		`	•			
₹Vagina:						
Sarcoma						
		0/53	(0%)	0/53 (0%)	0/52 (0%)	
		0/53	(0%)	0/53 (0%)	0/53 (0%)	
		0/50	(0%)	1/53 (2%)	0/53 (0%)	
Overall Incidence	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
₹Vagina:	•••••					
Schwannoma Malignant						
		0/53	(0%)	0/53 (0%)	0/52 (0%)	
		0/53	(0%)	0/53 (0%)	0/53 (0%)	
		0/50	(0%)	0/53 (0%)	1/53 (2%)	
Overall Incidence	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 39

		Male			Female			
#Vagina: Squamous Cell Carcinoma								
·						1/53 (2%) 0/53 (0%)	0/53 (0%) 0/53 (0%)	1/52 (2%) 0/53 (0%)
Overall Incidence					Total	0/50 (0%) 2/473 (0.42%)	0/53 (0%) Mean 0.42%	0/53 (0%) SD 0.84%
#Vagina:	•••••				•••••			
Squamous Cell Papilloma						0/53 (0%) 0/53 (0%) 0/50 (0%)	0/53 (0%) 1/53 (2%) 0/53 (0%)	0/52 (0%) 0/53 (0%) 0/53 (0%)
Overall Incidence					Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
#Zymbal's Gland: Carcinoma	•••••						•••••	
Carcinoma		1/50 (2%)				0/53 (0%) 0/53 (0%) 0/50 (0%)	0/53 (0%) 0/53 (0%) 0/53 (0%)	0/52 (0%) 1/53 (2%) 0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
#Zymbal's Gland: Carcinoma or Adenoma								
Salsing of Additiona		1/50 (2%)				0/53 (0%) 0/53 (0%) 0/50 (0%)	0/53 (0%) 0/53 (0%) 0/53 (0%)	0/52 (0%) 1/53 (2%) 0/53 (0%)
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/473 (0.21%)	0/53 (0%) Mean 0.21%	0/53 (0%) SD 0.63%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied